

REMARKS

The Examiner is again thanked for her careful review of the present patent application.

As an initial matter, the claims have been amended. Full support for the claim amendments can be found throughout the specification. The percentage of dextrose in the saccharide, for instance, is discussed at page 8. The addition of saccharide to a starch hydrolyzate is disclosed, for instance, at page 8 lines 10-11.

Applicants continue to present claims directed towards an extrusion reaction product. The subject matter of claim 1 is a unique mixture of saccharide-derivatized oligosaccharides that is not taught in or suggested by the prior art.

Section 112

The Section 112 rejection as to digestibility is now moot. The Office Action referred to the “majority” claim limitation in setting forth the rejection, but did not enter a specific rejection of this term. It is submitted that there is nothing indefinite about this term as used in the claims.

The Section 112 objection to claim 36 is now moot.

Section 102 Rejection over Okhuma

Applicants respectfully submit that the Section 102 rejection over Okhuma should not be repeated as applied to the pending claims. Claim 1 specifies that the starting material includes a saccharide and a mixture of malto-oligosaccharides of higher molecular weight. As specified in the amended claim, the saccharide includes at least 50% dextrose, and the starting material is a starch hydrolyzate mixture to which additional saccharide has been added. As discussed in the specification, at page 8, the addition of dextrose is believed to serve as a processing aid in the extrusion reaction.

Okhuma does not disclose or suggest a product in which the starting saccharide includes 50% dextrose, nor a starting material comprising a starch hydrolyzate to which

additional saccharide has been added. In the referenced portion of Okhuma's disclosure, starch is treated with hydrochloric acid, and the resulting product is extruded. There is no teaching or suggestion of the dextrose content of this starting material. In any event, there is no suggestion of adding additional saccharide to a hydrolyzed starch. Okhuma is completely silent as to this feature of the claimed invention.

Moreover, Okhuma not only fails to anticipate, Okhuma would not be useful in connection with a Section 103 rejection. Okhuma teaches away from a product in which a majority of bonds are 1,4 bonds. Only Sample No. 1 (in Table 4, bridging columns 14 and 15) is the content of 1,4 bonds said to constitute a majority of the linking bonds. In the remaining samples, there are fewer 1,4 bonds, and the digestibility is lower. Okhuma's goal is to reduce the digestibility of the resulting product – the title of the patent is "Indigestible Dextrin," and the stated goal of the invention is "indigestible dextrin prepared by heat-treating corn starch with the addition of acid." Col. 1 ll. 6-8. In the passages following Table 4, Okhuma teaches that the digestibility can be correlated to the amount and type of glycoside linkages. At column 8, lines 38 *et seq.*, Okhuma reports that the 1,4- and 1,6- linkages do not correlate with the amount of indigestible components.

Okhuma thus teaches away from providing a product with a majority of 1,4 bonds. Following the teachings of Okhuma, one would be motivated to prepare a product with a smaller proportion of 1,4 bonds. In retrospect, this is not surprising, because Okhuma's goal is to provide an indigestible product. As discussed in the M.P.E.P., at section 706.02, the obviousness analysis must incorporate the teachings of the reference:

The distinction between rejections based on 35 U.S.C. 102 and those based on 35 U.S.C. 103 should be kept in mind. Under the former, the claim is anticipated by the reference. No question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. Whereas, in a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made.

Additionally, one of ordinary skill would not have been motivated to select, as the mixture to be extruded, a mixture in which the saccharide component is at least 50% dextrose. Okhuma is silent as to the addition of dextrose to a starch hydrolyzate, and does not teach or suggest the advantages thereof.

Thus, the rejection over Okhuma should not be repeated as against the pending claims.

Section 102 rejection over Meyers, et al.

The Meyers reference purports to disclose a use of FIBERSOL in chewing gum. This product is discussed and differentiated in the specification of the present application. FIBERSOL is sold by Matsutani America, and is described in numerous Matsutani patents, including the above-referenced Okhuma patent. Meyers discloses simply a use of FIBERSOL. The Meyers patent is silent as to the method of preparation of FIBERSOL, and is largely silent as to its properties (although Meyers does recognize this product as being an “indigestible dextrin,” column 3, lines 15-18).

Attached to the previously filed Amendment, as Exhibits A and B, are printouts from Matsutani America’s website. These exhibits provide more detail as to FIBERSOL. In Exhibit A, FIBERSOL is characterized as a soluble dietary fiber (90% minimum fiber on a dry solids basis). The designation as “fiber” connotes an indigestible product, and a minimum of 90% fiber signifies that essentially the entirety of the FIBERSOL product is not subject to digestion. Exhibit A references this expressly: “The human digestive systems effectively digest only alpha 1,4 linkages; therefore the other linkages render the molecules resistant to digestion.” In Exhibit B, Matsutani further confirms that, per 100 grams of FIBERSOL, there are 95 grams total carbohydrates and 90 grams of dietary fiber. This exhibit confirms that essentially the entire product is indigestible.

Given the teachings of Matsutani’s Okhuma patent, FIBERSOL unquestionably is different from the product claimed in the present application. Okhuma reports a correlation between digestibility and 1,4 bonds. The FIBERSOL product has almost no digestibility (and hence, it would appear that Matsutani is not teaching a majority of 1,4 bonds). Contrary to the assertions in the Office Action, the Mungara declaration filed in

August of 2007 does not report a majority of 1,4 bonds in FIBERSOL. The Examiner may have arrived a majority figure by adding other types of bonds (e.g., 1,2,4 linkages) but these are not 1,4 bonds. Such bonds are not digestible, or are minimally digestible, by mammalian enzymes. The table at page 8 of the most recent response shows a value of 51.5% 1,4 bonds *if the Mungara data were represented in the form shown in the Fouache reference*. This should not be taken as a suggestion of the percentage of 1,4 linkages as expressed herein, or in the Mungara declaration.

Myers is, at best, cumulative to Okhuma. Neither Myers nor Okhuma can be applied as against the pending claims.

Section 102 Rejection over Yoshida

Applicants continue to traverse the rejection over Yoshida. As discussed in the previous response, in Yoshida, no bonds are created. There will be nothing other than alpha 1,4- and alpha 1,6- bonds. The amended claims specify a product with 1,2 and 1,3 bonds. For this reason, the argument set forth in the Office Action has now been overcome.

Section 102 Rejection over Fouache et al.

The product of Fouache is different from the claimed product. The Fouache reference indicates that the product is characterized by “a content of glucosidic linkages 1→4 can be between 42 and 50%.” This teaches that the Fouache product does not contain a majority of 1,4- linkages. The product of Fouache is hence different from the claimed product, and Fouache does not anticipate any pending claim.

Again, the data presented in Fouache is presented differently from the data presented in the Mungara declaration, and the data cannot be directly compared. Specifically, Dr. Mungara differentiated between the various types of carbohydrates in the molecules, while the Fouache reference does not. For instance, Dr. Mungara counts a 1,4-linkage separately from a 1,2,4-linked carbohydrate. Fouache counted these linkages as a single 1,2 and a single 1,4 linkage, and did not count this 1-4 linkage separately from

other 1,4-linkages when reporting the total number of 1,4-linkages. For purposes of digestibility, however, the differences between a simple 1,4- linkage and a carbohydrate that has multiple linkages are substantial. Recalculating the Mungara data and presenting it in the form provided by Fouache yields the following:

	NUTRIOSE	FIBERSOL	Sample 1	Sample 3
1,2- bonds	9.8	9.9	7.8	5.9
1,3- bonds	9.9	8.3	7.8	6.4
1,4- bonds	49.6	51.5	59.7	67.2
1,6- bonds	30.7	30.1	24.3	19.5

The Office Action has indicated that the Examiner has added the number of “4” linkages to arrive at a 57.7%. This is not the same as a majority of 1,4 bonds, however.

Additionally, Fouache fails to teach a product prepared by extruding a mixture of a starch hydrolyzate with saccharide.

Section 102/103 Rejection over Stahl

Applicants maintain that the Stahl reference is irrelevant. Stahl discloses several carbohydrates that have been modified with various enzymes. In Example A1, which is the portion of Stahl’s specifically relied upon by the Examiner, maltodextrin was derivatized with glucose and a *leuconostoc* enzyme. *Leuconostoc* enzymes are well known in the art. As with most other enzymes, *leuconostoc* enzymes are very specific in their action. A product resulting from a *leuconostoc*-catalyzed reaction will consist almost exclusively of a carbohydrate that is linked with alpha-1,6- bonds. In some embodiments there may be small portions of alpha-1,2- or alpha-1,3- bonds. Nonetheless, the enzymatic reaction is very specific and characteristic, and results in a product that is very well defined.

The undersigned acknowledges the doctrine expressed by the Examiner that “the patentability of a product does not depend on its method of production.” Nonetheless, where the claimed product is very substantially different from the prior art – in this case, because the claimed product has different types of bonds and a different distribution of linkages – the cited art cannot be the basis of the claimed rejections.

In this case, enzymatic reactions of the type disclosed by Stahl are extraordinarily *specific*. They produce carbohydrates and related byproducts of a distinct, characteristic profile. The profile of products prepared in accordance with the present teachings are markedly different from an enzymatically produced product. The Examiner has suggested that the specification of an extruder is “broad,” leading to an undefined product. To the contrary, the use of extruder would of necessity produce a product with a different carbohydrate profile than the *leuconostoc*-catalyzed reaction of Stahl.

Conclusion

For these reasons, withdrawal of all the rejections is respectfully requested.

Respectfully submitted,

Dated: 4/30/09

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